APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,940	12/05/2001	Jiangchun Xu	210121.427D3	8468

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EXAMINER	
ZHOU, SHUBO	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/010,940	XU ET AL.	
	Examiner	Art Unit	
	Shubo "Joe" Zhou	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a) In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-69 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-69 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction/Election Requirement

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-3, 14-17, 19-22 (in part for 19-22), and 64 drawn to a polypeptide, composition thereof, a fusion protein and a vaccine comprising the polypeptide, classified in Class 530, subclasses 300 and 350.

II. Claims 4-10, 18, 19-22 (in part for 19-22), 60-63, and newly added 65-69, drawn to polynucleotides, composition thereof, vaccine, expression vector, and host cells comprising the polynucleotides, classified in Class 536, subclass 23.1 and 24.1; Class 435, subclasses 320.1, and 325 and 419.

III. Claims 11-13, and 19-22 (in part for 19-22), and 56-59, drawn to an antibody, composition or vaccine comprising the antibody, classified in Class 530, subclass 387.1.

IV. Claims 23-24, and 33 (all in part), drawn to a method for inhibiting the development of cancer in a patient comprising administering a polypeptide, classified in class 514, subclass 2.

V. Claims 23-24, and 33 (all in part), drawn to a method for inhibiting the development of cancer in a patient comprising administering a polynucleotide, classified in class 514, subclass 44.

VI. Claims 23-24, and 33 (all in part), drawn to a method for inhibiting the development of cancer in a patient comprising administering an antibody, classified in class 424, subclass 130.1.

VII. Claims 31-32, and 33 (in part), drawn to a method for inhibiting the development of cancer in a patient comprising administering an antigen presenting cell, classified in class 424, subclass 93.1.

VIII. Claims 25-30, drawn to a composition or vaccine comprising antigen presenting cells, classified in class 435, subclass 325.

IX. Claims 34-36, drawn to a method of removing tumor cells from a biological sample comprising contacting a biological sample with T cells that specifically react with a prostate specific protein, and a method of inhibiting the development of cancer in a patient by administering said biological sample, classified in class 424, subclass 93.1. Note: claim 36, as written, depends from claim 50, which appears to be an typographical error and it should depend from claim 34.

X. Claim 37 (in part), drawn to a method for stimulating and/or expanding T cells comprising contacting T cells with a polypeptide, classified in class 514, subclass 2.

XI. Claim 37 (in part), drawn to a method for stimulating and/or expanding T cells comprising contacting T cells with a polynucleotide, classified in class 514, subclass 44.

XII. Claim 37 (in part), drawn to a method for stimulating and/or expanding T cells comprising contacting T cells with an antigen presenting cell, classified in class 424, subclass 93.1.

XIII. Claim 38, drawn to an isolated T cell population, classified in class 435, subclass 325.

XIV. Claims 39-41, drawn to a method of inhibiting the development of cancer in a patient comprising the administration of T cells, classified in class 424, subclass 93.1.

XV. Claims 42-49, drawn to a method for determining the presence or absence of a cancer, or for monitoring the progression of cancer in a patient, comprising contacting a

biological sample from the patient with an agent that binds a tumor specific protein, classified in class 435, subclass 7.1.

XVI. Claims 50-55, drawn to a method for determining the presence or absence of a cancer in a patient, or for monitoring the progression of cancer in a patient, comprising contacting a biological sample from the patient with an agent that binds an oligonucleotide, classified in class 435, subclass 6.

2. The inventions are independent/distinct, each from the other because of the following reasons:

3. The inventions of Groups (II, V, XI and XVI), inventions of Groups (I, IV, X and XV), inventions of Groups (III and VI), inventions of groups (VII, VIII and XII), and the inventions of groups (IX, XIII and XIV) are independent/distinct inventions because the critical features of the inventions involve products that have different structures and have different functions and uses. For Groups Groups (II, V, XI and XVI), the critical feature is nucleic acids; for Groups (I, IV, X and XV), the critical feature is a polypeptide; for Groups (III and VI), the critical feature is an antibody; for groups (VII, VIII and XII), the critical products are antigen presenting cells, and for groups (IX, XIII and XIV), the critical products are T cells. It is acknowledged that various processing steps may cause a polypeptide to be directed as to its synthesis by a polynucleotide , however, the completely separate chemical types and distinct functions of the inventions of the nucleic acid, polypeptide, antibody support that they are separate inventions, and support the undue search burden if they were examined together. Additionally, polynucleotides, polypeptides, antibodies, antigen presenting cells and T cells have been most commonly, albeit not always, separately characterized and published in the literature, thus significantly adding to the search burden if examined together as compared to being searched separately.

4. The inventions of Groups II, V, XI and XVI are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acids of Group II can be used in the distinct processes of the inventions of Groups V, XI and XVI, which are processes for inhibiting the development of cancer in a patient, for stimulating and/or expanding T cells, etc. These processes comprise distinct steps, involving distinct reagents, and produce distinct results, hence are materially distinct.

5. The inventions of Groups I, IV, X, and XV are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the polypeptides of Group I can be used in the distinct processes of the inventions of Groups IV, X, and XV, which are processes for inhibiting the development of cancer in a patient, for determining the presence or absence of a cancer, for monitoring the progression of cancer in a patient. These processes comprise distinct steps, involving distinct reagents, and produce distinct results, hence are materially distinct.

6. The inventions of Groups III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antibody of Group III can be used in the process of the invention of Group VI, which is for inhibiting the development of cancer in a

patient. The antibody can also be used for purification of the protein it binds to, which is a distinct usage because it involves distinct steps and reagents and product different results.

7. The inventions of Groups VII, VIII and XII are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antigen presenting cells of Group VIII can be used in the distinct processes of the inventions of Groups VII and XII, which are for inhibiting the development of cancer in a patient and for stimulating and/or expanding T cells. These processes comprise distinct steps, involving distinct reagents, and produce distinct results, hence are materially distinct.

8. The inventions of Groups IX, XIII and XIV are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the T cells of Group XIII can be used in the distinct processes of the inventions of Groups IX and XIV, which are for removing tumor cells from a biological sample and for inhibiting the development of cancer in a patient. These processes comprise distinct steps, involving distinct reagents, and produce distinct results, hence are materially distinct.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Sequence Election Requirement Applicable to All Groups

10. In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic acid sequence (See MPEP 803.04). It is noted that the multitude of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement.

MPEP 803.04 states:

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

11. Examination will be restricted to only the elected sequence.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

14. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to

retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on 571-272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst William Phillips whose telephone number is 571-272-0548, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shubo (Joe) Zhou, Ph.D.

Patent Examiner

19 March 2006

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER